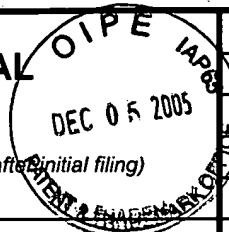


**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)



Application Number	10/773,986
Filing Date	February 5, 2004
First Named Inventor	Jenny Louie-Helm
Art Unit	1618
Examiner Name	Blessing M. Fubara
Attorney Docket Number	3100-0003.10

Mail Stop **Amendment**

**ENCLOSURES (Check all that apply)**

- No fee due
- Fee(s) due: \$ \_\_\_\_\_
  - Check enclosed
  - Charge Deposit Account No. 18-0580
  - 37 CFR § 1.16
  - 37 CFR § 1.17
- The Commission is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 18-0580
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- Amendment/Response
  - After Final
  - Affidavits/declaration(s) - \_\_\_\_\_ Affidavits/declaration(s)
  - \_\_\_\_\_-Month Extension of Time

- Terminal Disclaimer
- Information Disclosure Statement & PTO-1449 Form(s)
  - Copies of cited reference (EH-ES)
- Response to Missing Parts / Incomplete Application
  - Declaration(s) by Inventor(s)
- Preliminary Amendment
- Updated Application Data Sheet
- Drawing(s) - \_\_\_\_\_ Sheets
- Compact Disk(s) - \_\_\_\_\_ CD(s)
- Petition
- Power of Attorney & Address Indication Form

- Revocation of & New Power of Attorney, Address Indication Form
- Request for Refund
- After Allowance Communication to a Technology Center (TC)
- Appeal Communication to Board of Appeals and Interferences
- Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
- Other Enclosure(s) (see remarks):

**Claim Count**

Total Claims	Extra Claims	New Claim No.
_____	- 20 =	_____
Independent Claims	- 3 =	_____

**REMARKS**

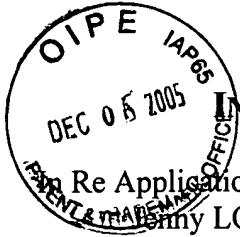
**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual Name (print/type)	David A. Sadewasser, Reg. No. 55,587 Reed Intellectual Property Law Group	Telephone	(650) 251-7700
Signature	<i>David A. Sadewasser</i>	Date	November 30, 2005

**CERTIFICATE OF TRANSMISSION/MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Name (print/type)	Joe Clark		
Signature	<i>Joe Clark</i>	Date	November 30, 2005



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Re Application of:  
Jenny LOUIE-HELM et al.

Serial No.: 10/773,986

Confirmation No.: 7141

Filing Date: February 5, 2004

Group Art Unit: 1618

Title: FORMATION OF AN ERODIBLE, GASTRIC RETENTIVE ORAL DOSAGE FORM  
USING IN VITRO DISINTEGRATION TEST DATA

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This is an Information Disclosure Statement submitted for the Examiner's consideration.  
Applicants respectfully request that the Examiner review and make of record the references  
identified below.

A PTO-1449 form listing the references accompanies this paper. Applicants would  
appreciate the Examiner's initialing and returning the form to indicate that the references have  
been reviewed and made of record. The references are as follows:

U.S. PATENT DOCUMENTS		
Document No.	Issue Date or Publication Date	Name of Patentee or Applicant
4,910,021	3/20/90	Davis et al.
6,248,363	6/19/01	Patel et al.
6,562,375	5/13/03	Sako et al.
2003/0091630 A1	5/15/03	Louie-Helm et al.
2003/0133985 A1	7/17/03	Louie-Helm et al.
2003/0152622 A1	8/14/03	Louie-Helm et al.
2004/0185105 A1	9/23/04	Berner et al.

**NONPATENT DOCUMENTS**

BLOEM et al., "A controlled trial of a slow-release form of furosemide in hypertension," Curr. Ther. Res. (1981) 29:577-583.

BOLES PONTO et al., "Furosemide (frusemide): a pharmacokinetic/pharmacodynamic review," (Parts I and II), Clin. Pharmacokinetics (1990) 18:381-471.

NONPATENT DOCUMENTS

CONTE et al., "Modulation of the dissolution profiles from Geomatrix® multi-layer tablets containing drugs of different solubility," Biomater. (1996) 17:889-896.
GABR et al., "Formulation and evaluation of buffered floating furosemide delivery systems," S.T.P. Pharma Sci. (2000) 10:181-186.
GUSLER, et al., "Pharmacokinetics of metformin gastric-retentive tablets in healthy volunteers," J. Clin. Pharmacol. (2001) 41:655-661.
HUBER et al., "Utilization of hydrophilic gums for the control of drug release from tablet formulations. I. Disintegration and dissolution behavior," J. Pharmac. Sci. (1966) 55:974-976.
IANNUCCELLI et al., "PVP solid dispersions for the controlled release of furosemide from a floating multiple-dose unit system," Drug Dev. Indus. Pharm. (2000) 26:595-603.
KANIWA et al., "The bioavailability of flufenamic acid and its dissolution rate from capsules," Intl. J. Clin. Pharmacol., Ther. Toxicol. (1983) 21:56-63.
KORSMEYER et al., "Mechanisms of solute release from porous hydrophilic polymers," Intl. J. Pharmac. (1983) 15:25-35.
MENON et al., "Development and evaluation of a monolithic floating dosage form for furosemide," J. Pharmac. Sci. (1994) 83:239-245.
UCHINO et al., "Clinical pharmacokinetics and diuretic effect of furosemide in plain tablet and retard capsule with normal subjects and cirrhotic patients," J. Pharm. Dyn. (1983) 6:684-691.
WAKELKAMP et al., "The influence of frusemide formulation on diuretic effect and efficiency," J. Clin. Pharmacol. (1999) 48:361-366.

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any of the above references constitutes prior art to the present application within the meaning of 35 USC § 102.

As applicants have not yet received a first Action on the merits, no fee is required for filing this Information Disclosure Statement. If, however, the PTO finds that for some reason a fee is found to be necessary, our Deposit Account No. 18-0580 may be charged therefor.

Respectfully submitted,

By:

  
\_\_\_\_\_  
David A. Sadewasser  
Registration No. 55,587

REED INTELLECTUAL PROPERTY LAW GROUP  
1400 Page Mill Road  
Palo Alto, California 94304  
(650) 251-7700 Telephone  
(650) 251-7739 Facsimile

Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

OPIE 1108

of

1

*Complete if Known*

Application Number	10/773,986
Filing Date	February 5, 2004
First Named Inventor	Jenny LOUIE-HELM
Art Unit	1618
Examiner Name	Blessing M. Fubara

Attorney Docket Number

3100-0003.10

<b>U.S. PATENT DOCUMENTS</b>						
Examiner Initials*	Cite No.	Document No.	Issue Date or Publication Date	Name of Patentee or Applicant of Cited Document	Class	Subclass
BM	DEC 05 2005	10,021	3/20/90	Davis et al.		
EB	TRADEMARKS	6,248,363	6/19/01	Patel et al.		
EC		6,562,375	5/13/03	Sako et al.		
ED		2003/0091630 A1	5/15/03	Louie-Helm et al.		
EE		2003/0133985 A1	7/17/03	Louie-Helm et al.		
EF		2003/0152622 A1	8/14/03	Louie-Helm et al.		
EG		2004/0185105 A1	9/23/04	Berner et al.		

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document No.	Publication Date	Country	Class	Subclass	T

## OTHER DOCUMENTS — NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), Title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	EH	BLOEM et al., "A controlled trial of a slow-release form of furosemide in hypertension," Curr. Ther. Res. (1981) 29:577-583.	
	EI	BOLES PONTO et al., "Furosemide (frusemide): a pharmacokinetic/pharmacodynamic review," (Parts I and II), Clin. Pharmacokinetics (1990) 18:381-471.	
	EJ	CONTE et al., "Modulation of the dissolution profiles from Geomatrix® multi-layer tablets containing drugs of different solubility," Biomater. (1996) 17:889-896.	
	EK	GABR et al., "Formulation and evaluation of buffered floating furosemide delivery systems," S.T.P. Pharma Sci. (2000) 10:181-186.	
	EL	GUSLER, et al., "Pharmacokinetics of metformin gastric-retentive tablets in healthy volunteers," J. Clin. Pharmacol. (2001) 41:655-661.	
	EM	HUBER et al., "Utilization of hydrophilic gums for the control of drug release from tablet formulations. I. Disintegration and dissolution behavior," J. Pharmac. Sci. (1966) 55:974-976.	
	EN	IANNUCCELLI et al., "PVP solid dispersions for the controlled release of furosemide from a floating multiple-dose unit system," Drug Dev. Indus. Pharm. (2000) 26:595-603.	
	EO	KANIWA et al., "The bioavailability of flufenamic acid and its dissolution rate from capsules," Intl. J. Clin. Pharmacol., Ther. Toxicol. (1983) 21:56-63.	
	EP	KORSMEYER et al., "Mechanisms of solute release from porous hydrophilic polymers," Intl. J. Pharmac. (1983) 15:25-35.	
	EQ	MENON et al., "Development and evaluation of a monolithic floating dosage form for furosemide," J. Pharmac. Sci. (1994) 83:239-245.	
	ER	UCHINO et al., "Clinical pharmacokinetics and diuretic effect of furosemide in plain tablet and retard capsule with normal subjects and cirrhotic patients," J. Pharm. Dyn. (1983) 6:684-691.	
	ES	WAKELKAMP et al., "The influence of frusemide formulation on diuretic effect and efficiency," J. Clin. Pharmacol. (1999) 48:361-366.	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.